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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,343	07/05/2005	Raymond Ming Wah Chau	2001-103US	8965

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/541,343	CHAU ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *5,8,9 and 11-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-7 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07/05/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/05/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claim 1-7 and 10, as drawn to SEQ ID NOS: 2, and 4-7, in the reply filed on 06/23/2006, is acknowledged. The traversal is on the ground(s) that, firstly, the groups are not [independent or] distinct AND a search of all groups would not pose an undue burden on the examiner. This is not found persuasive because a search of ANY analogue (e.g. any 6-mer peptide with some modicum of motor neuron effect) alone or in any conjugated form, is itself an undue burden (but the Examiner mistakenly forget to restrict all of these innumerable/undefined independent and distinct peptides out as well, and instead has addressed them through 112 1st issues), let alone a search of the distinctly described peptides of SEQ ID NOS: 2-7 (SEQ ID NO: 1 is native MNTF, and was not claimed (since a 33-mer) or searched). Secondly, that a restriction of SEQ ID NO: 3 from the other 5 sequences the Examiner was willing to search collectively through a search of SEQ ID NO: 2 (coextensively searchable core to SEQ ID NOS: 4-7), is unreasonable. This is not found persuasive because a separate and distinct search is required of SEQ ID NO: 2 which is not coextensive with a search of SEQ ID NO: 2. However, notwithstanding providing this information to Applicant for future reference in similar type applications where the basis for peptide restriction will arise, the Examiner has decided to take on this extra burden, and rejoin SEQ ID NO: 3, in the interest of compact prosecution for the benefit of Applicant, since SEQ ID NO: 3 is the only other distinctly described and searchable peptide in this application.

The requirement, as to the groupings, is still deemed proper and is therefore made FINAL. Claims 5, 8-9 and 11-22 are withdrawn as being drawn to non-elected subject matter.

Claim 5 is withdrawn because it is drawn to conservative substitutions TO the 7 to 32 consecutive amino acids corresponding to a polypeptide comprising SEQ ID NO: 2, which would take it out of the realm of the elected invention (peptide comprising SEQ ID NO: 2). Claims 1-7 and 10 are examined on the merits as drawn to any peptide analogue of 6-32 amino acid residues comprising a peptide selected from the group consisting of SEQ ID NOS: 2-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chau et al. (US 6,841,531).

The applied reference has a common inventor (Chau) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Chau et al. teaches a product of any polypeptide comprising SEQ ID NO: 3 (see e.g. claims 17-32) corresponds to native MNTF or SEQ ID NO: 1 of the present application. Where

unclear, the claims are read in light of their description. The description for what constitutes a polypeptide of SEQ ID NO: 3, includes any peptide fragments, including up to 100% fragments, of SEQ ID NO: 3 (col. 9, lines 20-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at any fragment of native MNTF in Chau et al., because Chau et al. advantageously teach/describes the invention to any polypeptide analogue or fragment of SEQ ID NO: 3, and one of ordinary skill in the art would have known/been enabled to cut up any fragment therein or substitute other known common amino acids at various loci therein, to arrive at the same in Chau et al. (at least as to the innumerable number of undefined analogues of 6 to 32 residue peptides comprising SEQ ID NO: 2, if not also to the 100% fragments of SEQ ID NOS: 2-7).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-7 and 10 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17-32 of U.S. Patent No. 6,841,531 (Chau et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '531 patent is drawn to the product of any polypeptide comprising SEQ ID NO: 3 (and it's use). The '531 SEQ ID NO: 3 corresponds to native MNTF or SEQ ID NO: 1 of the present application. Where unclear, the claims are read in light of their description. The description for what constitutes a polypeptide of SEQ ID NO: 3, includes any peptide fragments, including up to 100% fragments, of SEQ ID NO: 3 (col. 9, lines 20-27). Thus, '531 wholly contemplates, and renders obvious any analogue or fragment of SEQ ID NO: 3, and it would have been obvious to arrive at the same in the present application (at least as to the innumerable number of undefined analogues of 6 to 32 residue peptides comprising SEQ ID NO: 2, if not also to the 100% fragments of SEQ ID NOS: 2-7).

Claim Rejections - 35 USC § 112 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-7, and 10, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention is to any polypeptide analogue of 6 to 32 amino acids comprising SEQ ID NO: 2 (or 3).

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed genus of any polypeptide analogue of 6 to 32 amino acids comprising SEQ ID NO: 2 (or 3). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely,

although the specification describes 6 specific such analogues (SEQ ID NOS: 2-7), there is no other indication as to such analogues would be, or what amino acids would be within those other 6-32 residues, not taken up by either SEQ ID NOS: 2 or 3.

Thus, neither the claims nor the specification adequately describe the claimed genus. The invention, as to these other analogues is undescribed and therefore unsearchable/examinable (as well as potentially unduly burdensome (and subject to restriction) if such were present in not coextensively searchable). With the substantial variability among the broad genus, it is not clear as to what is intended as any analogue. One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the genus, namely any polypeptide analogue of 6 to 32 amino acids comprising SEQ ID NO: 2 (or 3).

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim is drawn to a peptide consisting of e.g. SEQ ID NO: 1. SEQ ID NO: 1 is known, native MNTF and 33 residues in length. It is unclear how SEQ ID NO: 1, a 33-mer, can depend form a claim which limits the size of the peptide analogue to 32 residues? It is suggested Applicant delete reference to SEQ ID NO: 1 in claim 7.

Observation

Notwithstanding the rejections under 35 USC 103 and Double Patenting rejections above, claims 1-7 and 10, as drawn to the specifically defined peptides "selected from the group **consisting of** SEQ ID NOS: 2, 3, 4, 5, 6, or 7", was not found to be reasonably taught or suggested, by the prior art of record. Were the claims amended to these specific six peptides (as opposed to any analogues fragment of 6-32 residues of native MNTF or SEQ ID NO: 1 (e.g. an analogue of 6 to 32 amino acids of SEQ ID NO: 2 or 3, the shortest fragments), along with persuasive arguments that the selection of these specific six peptides would not have been obvious analogue fragments selections from native MNTF, such may be favorably received. (Additionally, such an amendment with persuasive arguments, may allow Applicant to avoid an otherwise required Terminal Disclaimer, in which case the term of this patent would not appear to be extendable beyond February 28, 2025, the maximum term of the '531 patent).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 00/2/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654